REMARKS

Claims 22, 25, 31 have been amended. Claims 1-6, 11, 12, and 17 have been cancelled. Claims 27-29 are withdrawn. New claims 34-37 have been added.

Claims 7-10, 13-16, 18-26, and 30-37 remain in the application. Of these, claims 7; 8; 13; 18; 19; 20; 21; 22; and 31 are the independent system claims, and claim 25 is the independent method claim.

The Applicant appreciates the Examiner's time and attention during the interview on 7/12/2006. Prior to the interview, Applicant had filed an Amendment A in response to the Office Action mailed 11/15/2005. To recap Amendment A:

(1) The Examiner had indicated that claims 7-10, 13-16, and 18-21 would be allowable if placed into independent form. Claims 7 and 8 were amended to incorporate the subject matter of claims 1 and 6 (which have been cancelled). Claim 13 was amended to incorporate the subject matter of claims 1, 11, and 12 (which have been cancelled). Claim 14 was amended to correct a typographical error. Claims 18-21 were amended to incorporate the subject matter of claim 1 (which has been cancelled). Amended claims 7, 8, 13, and 18-21 were also amended to remove the inferential recitation of the body.

(2) New dependent claim 30 defined the subject matter defined in original dependent claim 21. New independent claim 31 was similar to allowed independent claim 22, except with "on an external skin surface at or near a targeted neural or muscular region" removed. New dependent claims 32 and 33 repeated the subject matter of allowed dependent claims 23 and 24.

(3) The Examiner had indicated that method claims 25 and 26 were indefinite, and recommended writing out structural detail of apparatus claims rather than making reference to them. Claim 25 was amended to include the structural detail as presented in the new independent claim 31. Original claim 26 depended from amended claim 25.

During the interview, the Examiner suggested further amendments to claims 22, 25, and 31, to clarify "instructions" to distinguish between end-of-life battery timeouts versus battery replacement using a pill-based medication regime, to define the batteries as being "disposable," and to define the instructions are being prescribed by clinicial/caregiver. This Amendment B amends Claims 22, 25, and 31 in a manner discussed during the interview.

New dependent claims 34-37 (dependent upon amended claims 22, 25 or 31) have been added to further define the prescribed battery replacement regime as comprising the replacement of the disposable battery repeated at least on about a daily or weekly basis. Support for the new dependent claims 34-37 can be found at page 3, line 10, and page 13, line 21.

During the interview, one of the joint inventors Robert B. Strother (Vice President of Engineering and Chief Technology Officer at NDI Medical, LLC, which holds exclusive rights to the technology) discussed a neuromuscular stimulation system, as defined in currently amended claim 31. Mr. Strother also discussed examples of desired neuromuscular stimulation outcomes and the prior electrical stimulation therapies used with these outcomes. The prior electrical stimulation therapies discussed included surface electrode stimulation (TENS) and implanted stimulators. Problems associated with both TENS and implanted stimulators were also identified.

Mr. Strother displayed a prototype of a neuromuscular stimulation assembly comprising a portable carrier that is configurable to be worn by the patient, a percutaneous lead and electrode that is able to provide highly selective stimulation, and a seven day pill case or organizer that included a disposable battery, or "pill," for each day. Mr. Strother described how the specification likens the battery to a "pill," the pill being a dose of power for the stimulation circuitry as a medicine pill provides a dose of medication for a prescribed pill-based medication regime.

Published application U.S. 2002/0077572 to Fang et al. (Fang), and U.S. patent no. 6,026,328 to Peckham et al. (Peckham) were also discussed. For the sake of a complete record, Applicant is submitting with Amendment B a supplemental information disclosure statement that includes marketing information directed to a commercial embodiment of a device disclosed in Fang.

Amended claims 22, 25, and 31 define a neuromuscular stimulation assembly comprising a carrier sized and configured to be worn by an individual. The carrier includes circuitry configured to generate a stimulation pulse. The carrier also includes a power input bay sized and configured to hold a disposable battery for the circuitry that can be released and replaced for powering the circuitry. The carrier further includes an electrode connection element that is sized and configured to electrically engage an electrode lead for an electrode that has been percutaneously implanted in a targeted tissue region, to percutaneously apply the stimulation pulse to the targeted tissue region. As now defined in amended claims 22, 25, and 31, the assembly includes instructions furnished by a clinician or caregiver or physician prescribing the release and replacement of the disposable battery according to a prescribed battery replacement regime, the prescribed battery replacement regime

comprising the replacement of the disposable battery on a prescribed repeated basis similar to administering a pill under a prescribed pill-based medication regime. As further defined in amended claims 22, 25, and 31, the assembly includes a supply of disposable batteries, each battery comprising a dose of power for the circuitry for administration according to the prescribed battery replacement regime.

Support for the "pill-based" prescribed battery replacement regime language in amended claims 22, 25, and 31 can be found, e.g., at page 3, lines 6-17, page 6, line 30 through page 7, line 3, page 13, lines 18-29, and page 18, line 27 through page 19, line 9. Support for the "disposable" language can be found at page 13, line 10. Support for the "clinician or caregiver or physician" language can be found at page 3, line 21, and page 21, line 25. In addition, independent claims 22, 25, and 31 have been amended to replace "recharging" with "powering." Support for this amendment can be found at page 3 lines 4-5.

As stated during the interview, it is Applicant's position that neither Fang nor Peckham fairly teach or suggest instructions furnished by a clinician or caregiver or physician prescribing the release and replacement of a disposable battery according to a prescribed battery replacement regime, the prescribed battery replacement regime comprising the replacement of the disposable battery on a prescribed repeated basis similar to administering a pill under a prescribed pill-based medication regime. In both Fang and Peckham, the battery is incidental to the stimulation regime and is replaced at the end of its battery life. The battery is included to provide only a source of power, with the battery selection typically being a compromise between the physical size of the battery and as long of a battery life as possible, i.e., the battery is typically as small as possible but provides as long of a battery life as possible. Neither Fang nor Peckham teach or suggest a prescribed battery replacement regime for replacing the disposable battery on a prescribed repeated basis similar to administering a pill under a prescribed pill-based medication regime, and providing a supply of disposable batteries for administration according to the prescribed battery replacement regime, each battery thereby comprising a dose of power for the circuitry, as defined in amended claims 22, 25, and 31. With the prescribed battery replacement regime (as with a prescribed pill-based medication regime), a caregiver/clinician/physician instructs the patient to remove and replace the disposable battery on a repeated basis (like taking a dose of medication in pill form) to administer to the circuitry a dose of power so the circuitry can generate a dose of neuromuscular stimulation. In this

way, the prescribed battery replacement regime defined in amended claims 22, 25, and 31 has the flavor of a prescribed pill-based medication regime, and not an end-of-life battery timeout.

Claims 7-10, 13-16, 18-26, and 30-37 are pending and believed to be in condition for allowance. As expressed during the interview, if the Examiner believes that questions or matters of clarification remain, such matters can be handled expeditiously by an interview, either in person or by telephone, to advance prosecution of this case, and the applicant remains committed to proceed on that basis.

Respectfully Submitted,

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NDI Medical, LLC\18533\00072\ AMENDMENT B